

# The Research Exemption to Patent Infringement for Medical Research: US, UK and German Perspectives

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## Topics for discussion

- The research exemption and medical research
  - United States
  - United Kingdom
  - Germany
- Case studies
  - Risk associated with using comparator products
  - Use of a 3rd party for R&D activities
  - Minimization of risk by shifting location of research

# The Research Exemption in the United States

- Two types of research exemptions under US law:
  - Common law exemption
    - “Very narrow and limited to actions performed for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry”  
*Madey v. Duke Univ.*, 307 F.3d 1351 (Fed. Cir. 2002)
    - Under *Madey v. Duke Univ.*, unlikely to be available for any commercial entity or academic institution
  - Statutory Exemption, 35 USC. § 271(e)(1)
    - “It shall not be an act of infringement to ... use ... or import into the United States a patented invention ... solely for uses *reasonably related* to the development and submission of information under a Federal law which regulates the ... use ... of drugs”

## 35 USC. § 271(e)(1)

- *Merck v. Integra*, 545 US 193 (2005) (remanded as 496 F.3d 1334)
  - Statutory text extends to all uses of patented inventions that are reasonably related to the submission of *any* information to the FDA
  - Necessarily includes preclinical studies of patented compounds that are appropriate for submission in the regulatory process
  - Under certain conditions, the exemption can include (1) experimentation on drugs that are not ultimately the subject of an FDA submission or (2) use of patented compounds in experiments that are not ultimately submitted to the FDA
- Must have a specific goal in mind; a “remote desire” to obtain FDA approval for products using the patented product or method is not sufficient. *See Third Wave Techs. v. Stratagene Corp.*, 381 F.Supp.2d. 891 (W.D. Wis. 2005).
- Commercial and marketing-related studies must be carefully evaluated to determine whether they are related to the submission of information to the FDA. *See Amgen v. Int’l Trade Comm’n*, 565 F.3d 846 (Fed. Cir. 2009).

## 35 USC. § 271(e)(1)

- Exemption is not necessarily limited to the use of patented compounds themselves
  - In *Classen v. King*, 466 F.Supp.2d 621 (D. Md. 2006), the court held that even if the defendant had infringed patented methods for identifying and commercializing new drugs, the use was protected by 35 USC. § 271(e)(1).
- Use of patented laboratory equipment is not exempt from infringement
  - In *Proveris v. Innovasystems*, 536 F.3d 1256 (Fed. Cir. 2008), the sale of an “optical spray analyzer” used to analyze the physical parameters of aerosol sprays was not exempt from infringement even though it was used exclusively to generate data for submission to the FDA, because the infringing device was not subject to FDA approval. Therefore, device did not need the safe harbor protection to avoid extending the patent term.

# The Research Exemption in the United Kingdom

- Statutory exemption

- Section 60(5)(b) of the Patents Act 1977

An act which, apart from this subsection, would constitute an infringement of a patent for an invention shall not do so if – (b) it is done for **experimental purposes** relating to the subject matter of the invention

- Limited case law

- Leading authority – *See Monsanto v. Stauffer* RPC [1985] 515
- Useful – *See decisions of the German Federal Supreme Court - Clinical Trials I and II*

# The Research Exemption in the United Kingdom

- The meaning of “experimental purposes”
  - Exemption may apply even if the purpose of the research has an ultimate commercial objective
  - Exemption may apply to early or late stage research
  - Broadly construed:
    - The research must serve to gain information and not merely to verify existing information
    - Limitation on scope of the exemption provided by the requirement that the experimental purpose relate to the subject of the invention



# The Research Exemption in the United Kingdom

- Words “relating to the subject matter of the invention”
  - No substantive statutory guidance or case law clarifying what is meant by:
    - **subject matter of the invention**, or
    - how **related** the experimental purposes must be to such subject matter
      - “relates to” = “real and direct connection with” the subject matter of the invention (*see Smith Kline & French Laboratories v. Evans Medical [1989] 1 FSR 513*)
  - Distinction between:
    - experimenting on – generally exempted
    - experimenting with – generally not exempted
      - Using the invention for the purpose for which it was patented without seeking to improve on it or otherwise discover something unknown about it or its use - regarded as use as a research tool

# The Research Exemption in the United Kingdom

- Late stage research – clinical trials
- Applications for marketing authorizations for generic drugs
  - Section 60(5)(i) Patents Act 1977 provides "An act which, apart from this subsection, would constitute an infringement of a patent for an invention shall not do so if ... it consists of
    - i. an act done in conducting a study, test or trial which is necessary for and is conducted with a view to the application of ... paragraphs 1 to 4 of article 10 of Directive 2001/83/EC, or
    - ii. any other act which is required for the purpose of the application of those paragraphs

# The Research Exemption in the United Kingdom

- Article 10 of Directive 2001/83/EC of the European Parliament and of the Council on the Community Code relating to medicinal products for human use
  - Bioequivalence studies
  - Pre-clinical and clinical tests “where a biological medicine, which is similar to a reference biological product does not meet the conditions in the definition of generic medicinal products, owing to, in particular, differences relating to raw materials or differences in manufacturing process ...”
- Clinical trials for new drug remain unaddressed

# The Research Exemption in Germany

- The legal framework for research exemptions in Germany:
  - Section 11 No.2 German Patent Act (PatG)  
**“Experimental use privilege”**
    - Case Law: “Clinical Trials I and II” decisions of the German Federal Court of Justice
  - Section 11 No.2b German Patent Act (PatG)  
**“Regulatory approval privilege”**

## Section 11 No.2 German Patent Act

### “Experimental use privilege”

- “Experimental use privilege”: Section 11 No.2 PatG
  - *“The rights conferred by the Patent shall not extend to acts done for experimental purposes relating to the subject matter of the patented invention.”*
  - Experimental use is exempted from patent protection.
  - Prerequisites:
    - acts done for experimental purposes
      - *“any systematic procedure aimed at obtaining new information is considered an **experiment**”* (BGH, “Clinical Trials I”)
    - they must relate to the subject matter of the patented invention
      - i.e., to the *“technical teaching and its beneficial utilization”* (BGH, “Clinical Trials I”)

## Case Law – German Federal Court of Justice (Bundesgerichtshof, “BGH”)

- “Clinical Trials I” – 1995
  - The BGH allowed for the conducting of trials directed toward obtaining data for approval of a pharmaceutical for a **second** indication.
  - Those experiments may be conducted during the lifetime of a third-party patent.
  - The BGH did not decide whether clinical trials could be conducted for the purpose of obtaining early regulatory approval/authorization for the **same** indication.
  - Various authors believe that the BGH implicitly expressed that “normal” clinical trials (i.e., for the **same** indication) would not be permitted.

## Case Law – German Federal Court of Justice (Bundesgerichtshof, “BGH”)

- “Clinical Trials II” – 1997
  - In its “**Clinical Trials II**”- decision in 1997, the BGH explicitly stated that clinical trials are permitted in cases where one of their purposes is to obtain data for clinical approval, even if such clinical trials are conducted for the **same** indication as that of the protected product.
  - They shall be permitted as long as the respective experiments are not performed **solely** to obtain data for clinical approval, but can be considered as also **aimed at discovering something unknown** about the used drug invention.

## Case Law – German Federal Court of Justice (Bundesgerichtshof, “BGH”)

- “Clinical Trials II” – 1997
  - In essence, this means that the generation of test data legitimately required to obtain regulatory marketing approval can qualify for the experimental use privilege, as long as the respective experiments are not performed ***solely*** for this purpose.
  - Exception: Clinical trials are **not** permitted if
    - the experiment is *not related* to the technical teaching
    - experiments/trials are conducted in a volume that would *not be justified* for the purpose of the experiments/trials or
    - experiments/trials were conducted for the *purpose of interfering* with the marketing efforts of the patentee.



## Section 11 No.2b German Patent Act (PatG)

### Regulatory approval privilege

- “**Regulatory approval privilege**” Section 11 No.2b PatG
  - Implemented EU regulations into German legislation in 2005 following the “**Clinical Trials II**”- decision by the BGH.
  - Derives its character from the US “**Roche-Bolar**”-**exception**.
  - In addition to the above-mentioned experimental use privilege, the “**Regulatory approval privilege**” applies not only to experimental use, but also to
    - **studies and trials**, and
    - the **consequential practical requirements necessary for obtaining an authorization** to market a drug.

## Section 11 No.2b German Patent Act (PatG)

### Regulatory Approval Privilege

- “Regulatory approval privilege” Section 11 No.2b PatG
  - Section 11 No.2b PatG is construed *broader* than No.2 as the privilege is not limited to experimental use and the acts do not need to relate to the subject matter of the patented invention.
  - Acts which are *objectively* necessary to obtain the regulatory pharmaceutical approval/authorization, but do not fall within the scope of 11 No.2 PatG, are privileged pursuant to Section 11 No.2b PatG.
  - The “Regulatory approval privilege” therefore also includes the manufacture of pharmaceuticals, provided that they are necessary to conduct studies and trials.

## Conclusion / Key factors

- The current situation in Germany is **rather liberal**.
- The “**experimental use privilege**” will not apply if above-mentioned ***exceptions*** stipulated by the BGH are fulfilled or in cases where the ***commercial use*** of the patented subject matter is the ***only*** reason for conducting experiments/trials (“*commercial use under disguise*”).
- In all other cases, as long as the experiments can be considered as also ***aimed at discovering something unknown*** about the used drug invention (even if the underlying reason for conducting the experiments mainly consists of commercial interests), the “**experimental use privilege**” will apply.

## Conclusion / Key factors

- Patent-utilizing preparatory acts, which are directly related to the aimed at regulatory approval/authorization, are now permitted under the **“Regulatory approval privilege”**.
- The privilege essentially eases the regulatory authorization/approval process for generic pharmaceuticals in Germany and enables generic companies to enter the market as soon as the term of protection for the originator pharmaceutical expires.

## Application to “up-stream” Activities

- Discovery +
  - If the discovery is aimed at improving and enhancing the patented subject matter, the **Experimental use privilege** will apply.
- Pre-clinical activities +
  - Generally covered by the **Experimental use privilege**, as long as its prerequisites are met, i.e.
    - acts done for experimental purposes
    - they must relate to the subject matter of the patented invention

## Application to “down-stream” Activities

- Clinical trials +
  - Exemptions are applicable to clinical trials.
- Regulatory filings +
  - Section 11 No.2b PatG “**Regulatory approval privilege**” applies.
    - Acts which are *objectively* necessary to obtain the regulatory pharmaceutical approval/authorization are privileged.

# CLE Code

# Case Studies



## Scenario 1

- X constructs Y's drug (for example, an antibody or chemical entity) using information taken from a patent held by Y
- X then uses Y's drug as a comparator with X's product candidate

## Scenario 1 – United States

- The use is exempt from infringement liability under § 271(e)(1), so long as the use is *reasonably related* to a submission for regulatory approval
  - Exemption goes beyond preclinical safety studies, and can include information regarding, e.g., pharmacological, toxicological, pharmacokinetic, and biological qualities of the drug (*See Merck v. Integra*)
  - The research need not actually result in the submission of information to the regulatory agency
  - Commercial and marketing studies must be carefully evaluated (*See Amgen*)
    - But even tests conducted in part for commercial purposes are likely exempt if they would produce information that would be given to the FDA (*See Genentech v. Insumed*, 436 F. Supp. 2d 1080 (N.D. Cal. 2006))
- If the accused product is a research tool, the answer is less clear.
  - Key consideration is whether the accused product is subject to regulatory approval (*See Proveris*)

## Scenario 1 – United Kingdom

- No case law considering application of the exemption to the use of a patented product in comparator testing
- Construction of Y's drug and comparator studies is not research into Y's drug BUT does the research relate to (having a real and direct connection to) Y's drug?
- General view – Use of patented product as a comparator should be exempt, otherwise non-exemption provides a result inconsistent with the aim of the patent system

## Scenario 1 – Germany

- X will benefit from the “Experimental use privilege”, as long as such comparison *relates to the subject matter of the patented invention*, i.e., is used to gain knowledge on the technical teaching of the patented product.
- If the accused product is a research tool
  - the “Experimental use privilege” will not apply, as the actions for experimental purposes must *relate to the subject matter of the patented invention*. As far as a research tool is merely being used as a means for finding new solutions, this will not be covered by Section 11 No.2 PatG.
  - the application of the “Regulatory approval privilege” is less clear. If the research tool is used to obtain results *directly* necessary for regulatory approval, the privilege will most likely apply.

## Scenario 2

- X engages a 3<sup>rd</sup> party to synthesize Y's drug
- 3<sup>rd</sup> party then provides Y's drug to X for use in comparator studies

## Scenario 2 – United States

- Same analysis as Scenario 1
- Both X and the 3<sup>rd</sup> party are exempt from infringement liability under § 271(e)(1), so long as the use is *reasonably related* to the submission of information to a regulatory agency
- The analysis is not affected by which party conducts the testing
- The Federal Circuit addressed this situation in *Forest Labs. v. Ivax Pharmaceuticals, Inc.*, 501 F.3d 1263 (Fed. Cir. 2007) Defendant Cipla supplied a product for testing, and the court determined that there was no infringement up until regulatory approval was received and both Ivax and Cipla were protected under § 271(e)(1)

## Scenario 2 – United Kingdom

- Same analysis as Scenario 1
- General view – if exemption applies to in-house synthesis and testing by X, it is likely to also apply for the benefit of X and the 3<sup>rd</sup> party when the same activities are outsourced by X to the 3<sup>rd</sup> party
- Tailored manufacture for specific experimental purposes
  - manufacture likely to be exempt
- General manufacture and then offered for sale “for research purposes only”
  - manufacture may not be exempt
- From X’s perspective, if X’s activities are exempt but 3<sup>rd</sup> party’s activities are not exempt, then can Y seek to make X jointly liable for 3<sup>rd</sup> party’s activities?
  - Joint tortfeasor?

## Scenario 2 – Germany

- 3<sup>rd</sup> party's actions:
- If 3<sup>rd</sup> party provides ***components/individual parts***:
  - Majority opinion : indirect patent infringement
    - The supplier does not benefit from the exemptions, Section 10 (3) PatG, because he does not himself conduct experiments
- If 3<sup>rd</sup> party provides the ***patented agent/substance***:
  - Controversially debated if this is a direct patent infringement pursuant to Section 9 PatG in Germany.
  - **Problem:** The exemptions include the manufacture of pharmaceuticals by the one performing the experiments.  
**But:** Does this also include the manufacture and supply by 3<sup>rd</sup> parties?



## Scenario 2 – Germany

### – Arguments *pro*:

- Without the supply by 3<sup>rd</sup> parties, only a very limited number of experiments could take place.
- The supply itself is not a heavier burden to the patentee than the manufacture for self-supply.

### – Arguments *contra*:

- The manufacture for self-supply is directly connected to the intended purpose of the experiment.
- The patented subject matter would be put into circulation and already commercially exploited.
- It would be in contradiction to Section 10 (3) PatG and the indirect infringement if components/individual parts are supplied.

## Scenario 2 – Germany

- It seems the majority opinion will therefore **not** grant 3<sup>rd</sup> party the benefit of an exemption.
- Therefore, 3<sup>rd</sup> party would be infringing upon Y's patent.
- X's actions:
- As X will be the one performing the experiments, he will benefit from the exemptions stipulated in Section 11 No.2 and/or 2b.

## Scenario 3: Location of Infringing Activity

- Does it make a difference where X conducts its infringing activity?
- UK perspective: If X conducts infringing research activities in the UK which do not infringe elsewhere, could an English court restrain the use elsewhere of the results derived from the infringing activity in the UK?
  - See *Kirin Amgen v. Transkaryotic Therapies* [2002] RPC 3
  - No realistic possibility of English courts restricting use of information abroad, but there may be a claim in the UK for damages suffered abroad which result from the infringement in the UK
- German perspective: If X conducts infringing research activities in Germany which do not infringe elsewhere, could a German court restrain the use elsewhere of the results derived from the infringing activity in Germany?
  - Similar situation as in the UK. No cross-border injunctions will be issued by German courts

## Scenario 3 continued: Infringing Activity in the US

- US perspective: If X conducts infringing research activities in the US which do not infringe elsewhere, could an American court restrain the use elsewhere of the results derived from the infringing activity?
  - American courts could enjoin the transfer abroad of information and equipment
  - Unlikely that a court would order surrender of the information to the patentee or its destruction (*See, Roche v. Bolar*, 733 F.2d 858, 865-67 (Fed. Cir. 1984) (discussing scope of injunctive relief)
  - Information generated from activities conducted ex-US to avoid US patents can be brought back to the US (*Bayer AG v. Housey Pharmaceuticals, Inc.*, 340 F.3d 1367 (Fed. Cir. 2003) (holding that § 271(g) applies to the manufacture of physical goods and not information))

## Questions & Answers



*Thank you*

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